IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Christopher H. Porter

Applic.: 10/821,383

Filed: 04/09/2004

For: PERCUTANEOUSLY IMPLANTABLE MEDICAL DEVICE CONFIGURED TO PROMOTE TISSUE INGROWTH

Examiner : Christopher Koharski
Art Unit: 3763

Amendment Responsive to Office Action dated 08/21/2008

Commissioner for Patents
Alexandria, VA 22313-1450

REMARKS

The Office Action dated 08/21/2008 has been carefully considered. It is noted that the prior final rejection has been withdrawn "in view of new prior art", that claims 1, 3 16 and 18-21 are currently pending, and that claims 10-12 have been withdrawn. It is further noted that claims 1, 3-9, 13-16, and 18-21 have been rejected under 35 U.S.C. 103 as being unpatentable over (1) Poirier (US 4,668,222) in view of de Groot (EP 0367354) and (2) Thramann (US 5,360,448) in view of de Groot. As a consequence of the new grounds of rejection, independent claims 1 and 16 are being canceled in favor of newly drafted independent claims 22 and 23, respectively. The current claim amendments are set forth with particularity in the attached Claim Listing. Note that the cancellation of claim 9 obviates the objection to the Specification.

The present invention is directed to a medical device 30 configured for implantation in a patient's soft tissue, e.g., in a patient's retro-auricular space 28. As discussed on page 4 of the Specification, it is intended to implant the device 30 in a recess 32 by surgically tunneling through space 28. Accordingly, the device 30 in accordance with the invention is configured with a lateral profile particularly suited to be longitudinally advanced through a surgically formed tunnel.

The device 30 is comprised of a housing body 42 having a lateral shoulder 60 and a stud 62 extending longitudinally from the shoulder. The longitudinal peripheral surface of the stud carries a longitudinal porous layer 30 for promoting soft tissue ingrowth. Additionally, the lateral surface of shoulder 60 carries a lateral porous layer which extends orthogonal to and abuts the longitudinal porous layer. The orthogonal porous layers function together to promote soft tissue ingrowth, promote vascularization and form an infection resistant barrier while also providing enhanced anchoring.

To enable the device 30 to be implanted by surgical tunneling, the housing body 42 defines a substantially uniform lateral dimension (see, e.g., Figures 5, 7, 12, 13A-C) and the lateral and longitudinal porous layers define lateral dimensions equal to or less than the housing body lateral dimension. This structural configuration allows the device 30 to be longitudinally advanced through a small surgically formed tunnel to subcutaneously implant the housing body 42 and percutaneously implant the projecting stud 62.

The Office Action initially rejects independent claims 1 and 16 (now cancelled in favor of new claims 22 and 23) under 35 USC 103 as unpatentable over newly cited Poirier in view of de Groot. Both of these references show percutaneously implantable access devices each having a flange or skirt carrying porous material useful for subcutaneous anchoring. In each case, the flange extends laterally beyond the lateral

dimension of the device body. Thus, neither of these references suggest a device construction suitable for implantation via surgical tunneling as contemplated by the present invention.

More particularly, note that Poirier describes multiple embodiments each including a flange or flat skirt, e.g., 22, 62, for subdermal anchoring. Further note that the Poirier flange has a lateral dimension, or diameter which is considerably larger than the lateral dimension of his device body. As a consequence, Poirier fails to suggest a device suited for implantation by surgical tunnelling. Rather, the Poirier device requires a relatively large surgical incision to allow the device flange to be inserted therethrough for subcutaneous implantation. The requirement to form a large incision, as contrasted with surgical tunneling, results in greater patient tissue damage, increased patient discomfort, and longer healing time.

The de Groot reference also teaches the use of a subdermal flange 2 for anchoring. As is apparent from de Groot's disclosure, his flange 2 has a much larger lateral dimension then the de Groot implant 10. Accordingly de Groot fails to suggest a device construction suited for implantation by longitudinally advancing the device through a surgically formed tunnel.

Applicant's new independent apparatus claim 22 has been carefully drafted to recite the distinguishing characteristics of embodiments of the invention which render them suitable for implantation by surgical tunneling and which afford the benefits identified in Applicant's Specification, i.e., promoting soft tissue ingrowth and vascularization, and forming an infection resistant barrier. Thus, claim 22 recites that the housing body has a substantially uniform lateral dimension and that the longitudinally and laterally extending porous layers abut one another and have lateral dimensions which are no greater than the

housing body lateral dimension. These limitations structurally distinguish claim 22 over the Poirier and de Groot teachings and afford significant functional advantages over the cited prior art. Accordingly, favorable consideration is respectfully requested.

Applicant's new independent method claim 23 has been similarly drafted to define a method of "configuring a medical device for implantation by surgical tunneling". Claim 23 recites providing a housing body defining a "substantially uniform lateral dimension" and forming a longitudinal porous layer "having a lateral dimension no greater than said housing body lateral dimension" and forming a lateral porous layer "having a lateral dimension no greater than said housing body lateral dimension". Further, claim 23 recites that the lateral porous layer is positioned to abut the longitudinal porous layer. It is accordingly urged that claim 23 thus patentably distinguishes over the Poirier and de Groot teachings and favorable consideration is requested.

The Office Action also rejects independent claims 1 and 16 (now canceled in favor of new claims 22 and 23) under 35 USC 103 as unpatentable over newly cited Thramann view of de Groot. Thramann discloses a bone screw having a shaft including "longitudinally extending regions, one or more of which have bone ingrowth porous surfaces and alternate with regions having threaded surfaces."

The Office Action recognizes that Thramann fails to teach Applicant's pore size and porosity limitations (recited in claims 22 and 23) but contends that "it would have been obvious to use the porous materials of de Groot with the system of Thramann ". With due respect to the examiner's contention, it is nevertheless urged that the proposed combination of references is not well taken. Thramann is solely concerned with long term "fixation of the screw to the bone " whereas de Groot is concerned with anchoring in "soft tissue", "when no boney tissue is present". The respective references address very

different problems and propose distinct solutions. It appears that nothing, other than perhaps Applicant's disclosure, would prompt a combination of the Thramann and de Groot teachings. And, it is respectfully urged, that reliance on Applicant's disclosure represents the application of impermissible hindsight reasoning. As noted in MPEP 2142, "impermissible hindsight must be avoided and the legal conclusion must be reached on the facts gleamed from the prior art".

In any event, assuming arguendo that the combination of Thramann and de Groot was appropriate, nevertheless they fail to suggest the invention recited in claims 22 and 23. Note particularly that claim 22 recites orthogonal longitudinally and laterally extending porous layers positioned to abut one another, as clearly depicted in Applicant's drawings (e.g., Figures 5, 7, 8, 12). These limitations clearly structurally distinguish claim 22 over the cited art and yield the benefits stressed in the specification of promoting soft tissue ingrowth and vascularization, forming an infection resistant barrier, and providing enhanced anchoring.

Method claim 23 similarly distinguishes over the cited art by reciting that the lateral porous surface is positioned to orthogonally abut the longitudinal porous surface.

In view of the foregoing, it is urged that independent claims 22 and 23 patentably distinguish the present invention over the cited prior art and favorable consideration of these claims, along with remaining dependent claims 3-8 and 18-21, is courteously requested.

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Respectfully submitted,

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